3M ESPE

K120453

3. 510(k) Summary

3M ESPE
Dental Products

3M Center
St. Paul, MN 55144-1000
651 733 1110

MAR 19 2012

3M ESPE

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92.

510(k) Submitter..... 3M Company
3M ESPE Dental Products
3M Center, Building 260-2A-11
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Establishment Registration Number: 3005174370

Contact person..... Scott Erickson, RAC
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Date Summary was Prepared..... January 26, 2012

Trade Name..... Filtek™ Bulk Fill Flowable Restorative

Common Name(s)..... Tooth shade resin material

Recommended Classification..... Tooth shade resin material
(21 CFR 872.3690,
Product Code: EBF)

Predicate Devices:
Filtek™ Supreme Ultra Flowable Restorative (K100235)
Adaptable Composite Resin Restorative Material (K083841)
Revolution™ Formula 2 (K013647)
3M™ Dent II System (K981647)

Description of Device:
Filtek™ Bulk Fill Flowable Restorative, is a low viscosity, visible-light activated, radiopaque, flowable. This low stress flowable material is semi-translucent enabling a 4mm depth of cure. The restorative is packaged in capsules and syringes. The shades offered with Filtek™ Bulk Fill flowable are U (Universal), A1, A2, and A3. Filtek™ Bulk Fill flowable contains bisGMA, UDMA, bisEMA(6) and Procrylat resins. The fillers are a combination of ytterbium trifluoride filler with a range of particle sizes from 0.1 to 5.0 microns and zirconia/silica with a particle size range of 0.01 to 3.5 μm. The inorganic filler loading is approximately 64.5% by weight (42.5% by volume). A dental adhesive is used to permanently bond the restoration to the tooth structure.

Filtek™ Bulk Fill Flowable Restorative is a modification of predicate device Filtek™ Supreme Ultra Flowable Restorative. The formulation was modified to increase depth of cure, while decreasing polymerization shrinkage stress.

Indications for Use:
- Base under Class I and II direct restorations
- Liner under direct restorative materials
- Pit and fissure sealant
- Restoration of minimally invasive cavity preparations (including small, non stress-bearing occlusal restorations)
- Class III and V restorations
- Undercut blockout
- Repair of small enamel defects
- Repair of small defects in esthetic indirect restorations
- Repair of resin and acrylic temporary materials
- As a core build-up where at least half the coronal tooth structure is remaining to provide structural support for the crown

Technological Characteristics:
Filtek™ Bulk Fill Flowable Restorative contains bisGMA, UDMA, bisEMA(6) and Procrylat resins. The fillers are a combination of ytterbium trifluoride filler with a range of particle sizes from 0.1 to 5.0 microns and zirconia/silica with a particle size range of 0.01 to 3.5 μm. The inorganic filler loading is approximately 64.5% by weight (42.5% by volume). A dental adhesive is used to permanently bond the restoration to the tooth structure.

When irradiated by light, the methacrylate functionalities of the resins and fillers undergo, in conjunction with the photoinitiator system, a light-induced polymerization to form a hard composite that is bonded to the tooth structure with a permanent dental adhesive.

Substantial Equivalence:

Biocompatibility:
A Diplomate of the American Board of Toxicology has assessed the safety of Filtek™ Bulk Fill Flowable Restorative. Standard risk assessment techniques and consideration of FDA General Program Memorandum G95 and internationally recognized guidelines, including ISO 10993-1:2009 along with Parts 3, 5, 6, 10, 11, 12 and ISO 7405:2008, were used in this evaluation. The conclusion of the assessment is that the product is safe for its intended use.

Risk Management:
The environmental, health and safety (EHS) risks for Filtek™ Bulk Fill Flowable Restorative were evaluated using a process compliant with ISO 14971:2007, as well as specific procedures and practices outlined by 3M ESPE Dental Products Standard Operating Procedures. After application of risk control, all risks identified in the Filtek™ Bulk Fill Flowable Restorative risk assessment were deemed to be broadly acceptable.

Summary of Physical Tests:
This 510(k) submission includes data from bench testing to evaluate the performance of Filtek™ Bulk Fill Flowable Restorative compared to predicate devices Filtek™ Supreme Ultra Flowable Restorative, Adaptable Composite Resin Restorative Material and Revolution™ Formula 2. Standards utilized include ISO 4049:2009 and ISO 6874:2005. Properties evaluated include Compressive Strength, Diametral Tensile Strength, Flexural Strength, Flexural Modulus, Surface Hardness, Radiopacity, Water Sorption, Water Solubility, Cusp Deflection, Volumetric Shrinkage, Wear and Depth of Cure.

Conclusion:
Information provided in this 510(k) submission shows that Filtek™ Bulk Fill Flowable Restorative is substantially equivalent to the predicate devices, Filtek™ Supreme Ultra Flowable Restorative, Adaptable Composite Resin Restorative Material, and Revolution™ Formula 2 in terms of intended use, indications for use, physical properties and technological characteristics. Filtek™ Bulk Fill Flowable Restorative is substantially equivalent to the predicate devices Filtek™ Supreme Ultra Flowable Restorative and 3M™ Dent II System in terms of formulation.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

3M ESPE Dental Products
C/O Mr. William Sammons
Responsible Third Party Official
Intertek Testing Services
2307 East Aurora Road
Unit B7
Twinsburg, Ohio 44087

MAR 19 2012

Re: K120453
Trade/Device Name: Filtek™ Bulk Fill Flowable Restorative
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: EBF
Dated: March 12, 2012
Received: March 14, 2012

Dear Mr. Sammons:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

3M ESPE

4. Indications for Use Statement

Indications for Use

510(k) Number (if known): _____

Device Name: Filtek™ Bulk Fill Flowable Restorative

Indications for Use:

- Base under Class I and II direct restorations
- Liner under direct restorative materials
- Pit and fissure sealant
- Restoration of minimally invasive cavity preparations (including small, non stress-bearing occlusal restorations)
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- Repair of small defects in esthetic indirect restorations
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- As a core build-up where at least half the coronal tooth structure is remaining to provide structural support for the crown

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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